UTILITY PATENT APPLICATION

TO ALL WHOM IT MAY CONCERN

Be it known that I, W. Henry Wall, residing at 1758 Colt Drive, Dunwoody, Georgia 30341, a citizen of the U.S.A., have invented certain new and useful improvements in a

Oro-Pharyngeal Airway With Breath Monitor

of which the following is a specification.

Thomas, Kayden, Horstemeyer & Risley, L.L.P.
100 Galleria Parkway, N.W., Suite 1750
Atlanta, GA 30339-5948
Telephone 770-933-9500

I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231, on 11-20-03.

Express Mail No. EL 992 706 012 US

Mary N. Kilgore
Signature

TITLE OF INVENTION

Oro-Pharyngeal Airway With Breath Monitor

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation-in-part of U.S. Patent Application Serial No. 10/046,767 filed January 17, 2002.

FIELD OF THE INVENTION

[0002] This invention relates generally to an Oro-Pharyngeal Airway, and more specifically to an airway that can be combined with a carbon dioxide monitor, that is used for a sedated or unconscious patient, such as when a patient is under or recovering from anesthesia, for detecting the carbon dioxide in the breath exhaled from the patient.

BACKGROUND OF THE INVENTION

[0003] During surgical procedures, particularly when the patient is under or recovering from general anesthesia, it is highly desirable to monitor the carbon dioxide of the breath exhaled by the patient. The amount of carbon dioxide in the exhaled breath, particularly at the end of the respiratory cycle, known as $ETCO_2$, indicates the health of the patient, and can be used to forecast changing conditions of the patient.

[0004] The American Society of Anesthesiologists implemented a new standard mandating the use of carbon dioxide (CO_2) monitoring during all general anesthesia, whether in or out of the operating room, for both intubated and non-intubated patients.

This new standard of care necessitates recognition, support, and compliance by key personnel involved in the management and delivery of anesthesia and procedural sedation. As the use of procedural sedation expands beyond the operating room, implementation of the standard becomes relevant to a broad spectrum of settings including hospitals and ambulatory care facilities as well as office-based practices for medical, surgical, dental, and oral surgery offices. Capnography, the monitoring of carbon dioxide in the patient's expelled breath, significantly reduces patient's safety risks by giving the earliest detection of hypoventilation.

[0005] Some authorities indicate that capnography should now be considered an essential component of patient monitoring in all situations in which drugs are given that impact levels of consciousness, responsiveness, and airway protective reflexes.

[0006] Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag, and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide is to be performed unless invalidated by the nature of the patient procedure or equipment.

[0007] In addition, monitoring of other aspects of the patient's breath can also be beneficial, such as the detection of certain drugs, alcohol, DNA, antibodies (including tumor), blood sugar, billirubin, acetone, and other elements in organic and inorganic compounds that might be present in the body.

[0008] Preferably, the sample of the patient's breath should be collected next to the opening of the larynx at the end of the respiratory cycle so that the tested sample will have minimal dilution from the ambient air, therefore be a truer sample for analysis.

[0009] Respiration devices and alarm systems for such devices are known in the art. Alarms are provided for alerting an operator when a patient is not breathing or the patient's breathing is failing outside of a normal breathing pattern. Such respiratory devices that are provided with alarms are disclosed in U.S. Patents 3,798,629; 3,802,417; 3,961,627; 4,287,886; 4,366,821; 4,368,740; 4,413,632; 4,417,589; and in my prior U.S. Patent 4,651,746. However, it is desirable to monitor the breath exhaled by the patient at the larynx to provide the evaluation of breath undiluted by ambient air or other conditions of the throat and mouth.

[00010] Another desired situation for monitoring exhaled breath is that the intubation device that reaches the larynx should have the ability to perform several functions, such as insufflation of medication directly to the larynx area of the throat, aspiration of mucus from the throat, monitoring of the breath expelled from the larynx area of the throat, and maintaining a continuously open airway for continuous breathing by the patient, all without removal of the oro-pharyngeal airway from the throat. This is particularly important for infants and children of small size because the small change in condition can be traumatic for the smaller body. Early detection of the change in breath condition of the smaller patient might be critical.

[00011] It is to these problems and objectives that this invention is directed.

SUMMARY OF THE INVENTION

[00012] Briefly described, the present invention concerns a method and apparatus for monitoring the carbon dioxide of a patient's breath, particularly the portion of the breath

exhaled at the end of the respiratory cycle from the vicinity of the larynx of the patient's throat during the time when the patient is unconscious, as when the patient is recovering from general anesthesia or when the patient is otherwise incapable of communicating with the surgeon or other medical staff. The monitoring of the patient can be accomplished with a multi-function airway placed in the patient's throat that permits other procedures to be performed without removing the airway.

[00013] In the preferred embodiment, an oro-pharyngeal airway is provided for insertion into the patient's throat. The airway includes an elongated body that is curved to fit the shape of the throat and having a proximal end for placement at the mouth of the patient and a distal end that extends through the throat to the vicinity of the larynx. The elongated body is provided in different sizes and is shaped to be compatible with the size and shape of the patient's throat, by providing airways of different lengths and breadths. The proximal end of the body of the airway is sized and shaped for engagement by the person's mouth, having a radially extending protrusion configured to block the movement of the proximal end into the patient's mouth, thereby stabilizing the proximal end at the mouth of the patient, accessible to the physician.

[00014] The elongated body of the airway defines an open-ended passage extending through the length of the body and being open at the proximal and distal ends of the elongated body. A front conduit segment or nipple extends beyond the radially extending member, with its opening that is approximately coextensive with the open-ended passage. A second conduit segment is positioned between the nippple and the radially extending protrusion so that it will be located outside the patient's mount. The

second conduit segment extends approximately radially from the elongated body with its passage formed in a T-shaped intersection with the passages of the nipple and the elongated body. The T-shaped intersection of the passages is of larger breadth and volume than the open ended passage of the elongated body of the airway. The T-shaped intersection forms a plenum outside of the patient's mouth for the accumulation of the exhaled breath of the patient. This larger plenum chamber can accumulate the breath at the end of the respiratory cycle at the proximal end of the airway and progressively feed the end tidal to the monitor at the rate induced by the monitor for a more even measurement of the carbon dioxide or other gas to be detected and measured. The placement of the plenum at the nipple end of the airway allows the airway to include the plenum without increasing the external breadth of the airway that extends into the throat, thereby keeping the external breadth of the elongated body of the airway as small as practical.

[00015] External protrusions extend from the elongated body of the airway and are shaped to engage the facing surfaces of the throat of the patient and form breathing passages that straddle the elongated body and extend along and externally of the elongated body. This provides the patient with a pair of air passages formed along the throat regardless of the manipulation of the open-ended passage extending through the length of the elongated body of the airway.

[00016] When in use, the nipple typically will be connected to a suction device that can intermittently aspirate the throat of the patient through the open ended passage, clearing mucus from the throat and maintaining the air passages that straddle the airway open for

breathing. Also, a supply of oxygen can be connected to the same nipple for the purpose of supplying oxygen to the lungs of the patient. Other devices such as an insufflation device can be used to move airborne medication through the open-ended passage to the larynx and lungs. In the meantime, the radially extending conduit that intersects the air passage of the airway can remain closed by the use of a plug or by the attendant's finger covering the opening thereof for controlling the effectiveness of the aspiration or insufflation of the throat, or can be connected to a monitoring device that monitors the content of the exhaled breath of the patient, particularly the breath at the end of the respiratory cycle. The monitor can be a carbon dioxide monitor.

[00017] The monitoring device usually will include an open-ended flexible tube having a first end connected to the radially extending conduit of the airway and its other end connected to the monitoring device. This provides an uncontaminated source of the patient's breath taken at the larynx without dilution or contamination from other sources along the throat and mouth and ambient air about the mouth of the patient.

[00018] A monitor suitable for this use is a capnographic monitor. When the monitor detects an increase or decrease in the carbon dioxide of the patient's breath, this becomes a forecast as to the health of the patient. A noticeable increase in the detection of carbon dioxide indicates, for example, hypoventilation by the patient, whereas a noticeable decrease in the detection of carbon dioxide indicates, for example, recovery from hypoventilation by the patient. This information can be used to decide what drugs are to be used to stabilize the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[00019] Fig. 1 is a side view of the airway, showing the airway positioned in the throat of a patient, with the patient shown in dash lines, and with the monitor, oxygen supply and pump shown schematically connected to the airway.

[00020] Fig. 2 is a perspective illustration of the airway.

[00021] Fig. 3 is a side elevational view of the airway, partially in cross section to show the plenum at the proximal end of the airway.

[00022] Fig. 4 is a cross-sectional view of the elongated body portion of the airway, taken along line 4 of Fig. 3.

DETAILED DESCRIPTION

[00023] Referring now in more detail to the drawings in which like numerals indicate like parts throughout the several views, Fig. 1 shows a patient 10 that is intubated with the airway 12, with the airway extending to the larynx of the patient. The airway, shown better in Figs. 2-4, includes an elongated body 14 formed of a suitable substantially rigid material, such as a relatively light-weight thermoplastic that can be gas assisted injection molded into the detailed shape. The gas assisted injection method is in any conventionally known method. This is important to the invention to provide the smooth and precisely formed small exterior of the airway that can pass along the throat of the patient, particularly the small patient, while providing a thin wall for forming ample breadth of passage through the interior. While the shapes and sizes of the exterior surfaces of the device are important since they contact the patient, the shapes and sizes

of the internal surfaces of the elongated body 14 are not necessarily critical to the operation and function of the invention. Therefore, gas assisted injection molding is a suitable and most desirable form of manufacture of the device.

[00024] The elongated body 14 includes a proximal straight section 16 and a distal arcuate section 18. A pair of opposed, spaced, longitudinally extending parallel ribbon-like flange elements 20 and 22 are formed on opposite surfaces of conduit 24. An internal, open-ended passage 26 (Fig. 4) extends throughout the length of the elongated body 14. The passage 26 terminates in open end 28, with side ports 30 opening to the side of the conduit 24 at its distal end.

[00025] The flanges 20 and 22 protrude laterally of the conduit 24, and are sized and shaped to engage the facing surfaces of the throat of the patient, so that the throat surfaces and the flanges, together with the external surface of the conduit 24, form air passages 28 about the elongated body, so that the patient has open air passages to the outside along the entire length of the elongated body 14.

[00026] The proximal end 16 of the elongated body 14 terminates in radial protrusions 30 that are formed by a pair of radially extending flanges. This forms a rest for the airway, to rest against the lips of the patient when the patient is intubated with the airway, as shown in Fig.1.

[00027] A nipple or converging conduit section 32 is mounted to the proximal straight section 16 of the elongated body 14, with its passage 33 coextensive with the passage 26 of the elongated body 14. The nipple 32 is formed in a diverging shape so as to be compatible with a friction fit with interior surface of the end of a flexible conduit (not

shown) wedged onto the exterior surface of the nipple, when connecting other devices to the airway. In the alternative, the internal passage of the conduit section 32 can be formed in a converging configuration for the wedging of a smaller end portion of a flexible conduit into the passage. Moreover, other connector configurations can be utilized for screwing, clamping, or other conventional means of connecting the flexible conduit to the conduit section 32 of the airway.

[00028] A T-shaped connection is formed by radially extending conduit section 34, and its open-ended passage 36 communicates with the passage 26 of the elongated body 14 and passage 33 of nipple 32. Like the converging conduit section 32, the radially extending conduit section 34 can be of various shapes to expedite the connection of the end portion of an open-ended flexible tube.

[00029] It will be noted that the radially extending conduit section 34 is positioned on the distal side of the radial protrusion 30, so that the mouth of the patient will not interfere with access to the conduit section 34.

[00030] As illustrated in Fig. 1, a monitor, such as a carbon dioxide monitor 40, is connectable to the radially extending conduit section 34 of the airway 12, while other devices, such as an oxygen supply 42 and/or a spray pump 44, are connectable individually or together to the converging conduit section 32 of the airway. The dash lines 46 extending from monitor 40 represent flexible open-ended plastic tubing of conventional design. Similar flexible tubing 47, 48 connects the suction pump 44 and oxygen supply 42 to the nipple 32.

[00031] Fig. 3 illustrates the T-shaped intersection of the passage 36 of the radial conduit section 34 with the passages 26 and 33 of the nipple 32 and elongated body 14. The dimensions of the T-shaped intersection are of greater breadth than the passages 26 and 33, forming a plenum generally designated at 50 that is at least twice as large, preferably four times as large as the breadths of the nipple passage 33 and the open ended passage 26. The plenum is located at the proximal end of the airway, at a position beyond the radial protrusion 30 and beyond where the mouth of the patient is to be placed. This avoids the placement of the plenum in the elongated body of the airway where the size of the airway is to be kept as small as practical. The plenum 50 functions to accumulate a large volume of the exhaled breath from the larynx of the patient, preferably at the end of the respiratory cycle of the patient, forming a larger supply of exhaled breath with high content of carbon dioxide that can be delivered to the monitor at the rate induced by the monitor.

[00032] As stated above, the airway can be manufactured in different sizes for use with patients of different sizes. A different color is applied to each different size airway to designate the size of the airway. The color in the disclosed embodiment is carried by a collar 52 that surrounds the base of the nipple, but the color identifier can be applied in different ways, such as the material of the airway being formed in colors that correspond to the size of the airway.

OPERATION

[00033] The apparatus can be used in several ways, such as utilizing the suction pump 44 to withdraw mucus from the throat of the patient deep within the throat adjacent the larynx, using the oxygen supply 42 to supply the patient with oxygen, and utilizing the monitor 40 to analyze the breath of the patient, particularly the carbon dioxide content of the breath for the purpose of predicting the physical condition of the patient. Conventional valves (not shown) are used to open and close communication between the airway and the oxygen supply, the suction pump and the monitor so these devices can be use one at a time.

[00034] It will be noted that the distal end portion 18 of the elongated body 14 is placed deep within the throat, adjacent the larynx, so that its passage 26 opens through the open end 28 and the lateral air opening 29. This allows the suction pump 44 to withdraw the mucus from adjacent the larynx, and also allows the monitor 40 to monitor the condition of the breath at the larynx, before the breath passes through the outer portion of the throat, through the mouth into the atmosphere, thereby avoiding contamination of the breath with additional outside air or other conditions of the throat and mouth. Thus, a more pure sample of the content of the patient's exhaled breath can be obtained with this invention. In addition, the monitoring of the patient's exhaled breath can be continued without requiring further intubation of the patient, without interrupting the other intermittent functions of the airway, and without significant discomfort or injury to the patient.

[00035] In operation of the oro-pharyngeal airway 12, the device is inserted into the patient's mouth until the curved distal section 18 extends through the back of the patient's throat, adjacent the pharynx. In the meantime, the radial protrusion 30, in the form of oppositely extending flanges, comes to rest against the exterior of the patient's mouth, avoiding inadvertent movement of the proximal end further into the mouth of the patient. The flanges 20 and 22 engage the facing surfaces of the patient's throat, forming the air passages or channels 28. Since the flanges 20 and 22 extend along the entire length of the airway, the air passages formed on opposite sides of the elongated body will not be interrupted by any of the functions that are carried on internally of the airway. The patient is then able to breathe through the channels 28 that extend along the exterior of the conduit 24 of the elongated body 14.

[00036] In addition to the ability of the patient to breathe exteriorly of the elongated body 14, the patient can also breathe through the internal passage 26 of the airway, as long as the passage is open and not being used for other purposes.

[00037] When it is necessary to perform a throat evacuation to remove fluid, mucus, blood, etc. from the throat, a flexible tubular conduit represented by the dash lines 50 of Fig. 1, is frictionally engaged over the converging conduit section 32 of the airway. The suction pump apparatus 44 is connected to the distal end of the flexible tube and is operated to create a mild suction within the passage 26 of the airway 12, withdrawing such fluids from the patient's throat. This can be performed without removing the suction airway 12 from the patient's mouth.

[00038] Alternatively, insuflation of the patient's lungs can be accomplished by connecting the tube to a insuflation device, such as an oxygen supply apparatus 42 in order to inject a stream of oxygen through the passage 26 of the airway, through the distal end 28, down the patient's throat, to the patient's lungs.

[00039] During either the suction or oxygen supply operations, the patient is still able to breathe through the side air channels or passages 28 formed between the airway and the facing surfaces of the throat.

[00040] The radially extending conduit section 34 can be used as a valve by the attending physician, either covered or opened, to control the strength of the suction of the suction pump 44, by applying the attendant's fingertip to the passage 36 of the radially extending conduit section 34.

[00041] More importantly, the carbon dioxide content of the patient's exhaled breath can be monitored by the application of a flexible tube to the radially extending conduit section 34, and extending the other end of the tube to a monitor 40. This causes the exhaled breath of the patient to be moved directly to the monitor 40 without contaminating the sample of breath with ambient air adjacent the patient's mouth or other contaminants derived from the throat and/or mouth of the patient.

[00042] Although preferred embodiments of the invention have been disclosed in detail herein, it will be obvious to those skilled in the art that variations and modifications of the disclosed embodiments can be made without departing from the spirit and scope of the invention as set forth in the following claims.